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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20480

JUL 27 1992

MEMORANDUM

SUBJECT:

6(a)(2) Data: Over-Tolerance Residues of Thiabendazole on Citrus; Chemical

No. 60101; Branch No. 10168; DP Barcode No. D179437; MRID No.

42315701

FROM:

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THRU:

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TO:

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Merck, Sharp, & Dohme Research Laboratories has submitted preliminary residue data under FIFRA 6(a)(2) guidelines. When conducting crop field trials required for the reregistration of thiabendazole, residues in/on citrus were found to be greater than the established tolerance of 10 ppm (40 CFR § 180.242). Feed additive tolerances have been established for thiabendazole residues in citrus molasses at 20 ppm and dried citrus pulp at 35 ppm (40 CFR § 186.5550).

Experimental details were not provided with the residue data. The registrant has stated that the results should be considered preliminary, as they have not been audited as of the May 5, 1992 letter. A summary of the results is presented in Table 1.

RECOMMENDATION

CBRS presumes that the trials were conducted in accordance with the product labels. If label instructions (in these trials) were followed properly, it is apparent that over-tolerance residues of thiabendazole may occur. Therefore the registrant must either amend the product label to

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2

reduce the application rate (with supporting residue data) or propose a higher tolerance. According to the May 5, 1992 letter (Patricia Sheehy to Frank Rubis) Merck intends to propose a higher tolerance when the final results of the study are submitted to the Agency before the studies are due in April 1993. Since concentration has been observed in the citrus oil, and food/feed additive tolerances have not been established for oil, tolerances must be proposed for citrus oil as well. It appears from the results that several samples were re-assayed or trials were repeated. The registrant should completely explain what transpired during the course of the study to avoid confusion over the results.

cc: CLOlinger (CBRS), Circulate, List B File, RF, SF

H7509C:CBRS:CLOlinger:clo:CM#2:Rm 805B:305-5406: 7/27/92

RDI: ARRathman: 7/27/92 MMetzger: 7/27/92 EZager: 7/27/92

3

Table 1. Residues of Thiabendazole in/on Citrus

Site	Commodity	Fraction	Control Samples Range of Results TBZ ppm Found	Treated Samples Range of Results TBZ ppm Found
FL_	Orange - Mandarin	Fruit	0.04	2.99 - 3.39
FL	Orange - Navei	Fruit	0.04	4.89 28.56
FL	Orange - Valencia	Fruit	0.128 - 0.133	5.06 - 6.23
		Washed Fruit	0.05	0.92 - 0.94
		Juice	0.01	0.05 - 0.06
		Molasses	0.29 - 0.32	5.22 - 5.37
		Oil	0.53	14.03 - 14.25
		Finish Pulp	0.01	0.150 - 0.168
		Dry Pulp	0.42 - 0.48	8.55 - 8.62
FL	Orange - Valencia	Fruit	0.013	6.80 - 9.55
FL	Orange - Navel	Fruit	0.05 ³	12.03 - 17.78
FL	Orange - Mandarin	Fruit	0.05 - 0.08	10.19 - 10.86
FL	Grapefruit	Fruit	0.06	6.13 - 11.88
		Washed fruit	0.02 - 0.03	1.50 - 1.60
		Molasses	0.03 - 0.21	9.00 - 9.30
		Oii	0.11 - 0.22	13.31 - 15.07
		Finisher Pulp	< 0.01 - 0.02	0.11 - 0.14
		Dry Pulp	0.19 - 0.24	12.46
		Juice	<0.01	0.06
FL	Grapefruit	Fruit	0.123	6.55 - 10.09
CA	Lemons-	Fruit	0.03	5.02 - 5.36
CA	Grapefruit	Fruit	0.083	2.85 - 2.87
CA	Orange	Fruit	0.04 - 0.05	1.271
CA	Orange	Fruit	0.07 - 0.08	1.842

¹ Generally two values were reported for controls from each site.
² At least two determinations were reported for treated samples.
³ Average value reported.